IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HORIZON MEDICINES LLC, Plaintiff, v. ALKEM LABORATORIES LTD., Defendant.	Civil Action No. 18-1014-RGA

MEMORANDUM OPINION

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August 7, 2020

/s/ Richard G. Andrews
ANDREWS, U.S. DISTRICT JUDGE:

Before the Court is the issue of claim construction of one term in U.S. Patent No. 8,067,451 ("the '451 patent"). The Court has considered the parties' claim construction briefing and accompanying exhibits. (D.I. 68; D.I. 75; D.I. 76; D.I. 94; D.I. 100). The Court heard oral argument on November 13, 2019. (D.I. 86 [hereinafter, "Tr."]).

I. BACKGROUND

On July 9, 2018, Plaintiff Horizon Medicines LLC filed this action against Defendant Alkem Laboratories Ltd., alleging infringement of U.S. Patent No. 8,067,033 ("the '033 patent") and the '451 patent. (D.I. 1). Following a claim construction hearing, the Court ruled on the claim construction issues concerning the '033 patent. (D.I. 89.) The '451 patent is addressed to methods and oral dosage forms relating to the administration of ibuprofen. ('451 pat., Abstract).

II. LEGAL STANDARD

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (internal quotation marks omitted). "'[T]here is no magic formula or catechism for conducting claim construction.' Instead, the court is free to attach the appropriate weight to appropriate sources 'in light of the statutes and policies that inform patent law.'" *SoftView LLC v. Apple Inc.*, 2013 WL 4758195, at *1 (D. Del. Sept. 4, 2013) (quoting *Phillips*, 415 F.3d at 1324). When construing patent claims, a court considers the literal language of the claim, the patent specification, and the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977–80 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Of these sources, "the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d

at 1315 (internal quotation marks and citations omitted).

> "[T]he words of a claim are generally given their ordinary and customary meaning. . . . [The ordinary and customary meaning is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application."

Id. at 1312–13 (internal quotation marks and citations omitted). "[T]he ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted). "In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Id.* at 1314 (internal citations omitted).

When a court relies solely upon the intrinsic evidence—the patent claims, the specification, and the prosecution history—the court's construction is a determination of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015). The court may also make factual findings based upon consideration of extrinsic evidence, which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Phillips*, 415 F.3d at 1317–19 (internal quotation marks and citations omitted). Extrinsic evidence may assist the court in understanding the underlying technology, the meaning of terms to one skilled in the art, and how the invention works. *Id.* Extrinsic evidence, however, is less reliable and less useful in claim construction than the patent and its prosecution history. *Id.*

"A claim construction is persuasive, not because it follows a certain rule, but because it defines terms in the context of the whole patent." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." *Osram GmbH v. Int'l Trade*

Comm'n, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (internal quotation marks and citation omitted).

III. PATENT AT ISSUE

Claim 1 of the '451 patent is representative:

> An oral dosage in tablet form comprising
>
> a first portion that comprises 800 mg ibuprofen and a second portion that comprises 26.6 mg famotidine,
> wherein *a barrier layer comprising hydroxyl propyl methyl cellulose 2910, polyoxyethylene glycol 400, polysorbate 80, and titanium dioxide surrounds the second portion completely separating it from the first portion,*
> wherein upon storage of the oral dosage in tablet form at 40° C. and 75% humidity for one month, no more than about 0.5% total famotidine impurities is present in the oral dosage in tablet form;
> wherein the oral dosage in tablet form is formulated so that release of both the ibuprofen and the famotidine occurs rapidly at about the same time,
> wherein none of the oral dosage in tablet form, the famotidine, and the ibuprofen is enterically coated or formulated for sustained or delayed release,
> wherein the oral dosage in tablet form is for use according to a TID (three times per day) administration schedule for reducing the risk of developing ibuprofen-induced ulcers in a human patient requiring ibuprofen for an ibuprofen-responsive condition selected from the group consisting of rheumatoid arthritis, osteoarthritis, and pain from a condition other than rheumatoid arthritis and osteoarthritis wherein the human patient does not suffer at the times of administering from a condition characterized by hypersecretion of gastric acid and/or from active severe oesophagitis and/or Barrett's ulceration, and/or from gastroesophageal reflux disease.

IV. CONSTRUCTION OF DISPUTED TERMS

The term in dispute is:

"a barrier layer comprising hydroxyl propyl methyl cellulose 2910, polyoxyethylene glycol 400, polysorbate 80, and titanium dioxide surrounds the second portion completely separating it from the first portion" (claims 1, 10)

a. *Plaintiff's proposed construction:* no construction needed

b. *Defendant's proposed construction*: a single barrier layer consisting essentially of hydroxyl propyl methyl cellulose 2910, polyoxyethylene glycol 400, polysorbate 80, and titanium dioxide surrounds the famotidine portion completely separating it from the ibuprofen portion

c. *Court's construction*: a barrier layer consisting essentially of hydroxyl propyl methyl cellulose 2910, polyoxyethylene glycol 400, polysorbate 80, and titanium dioxide surrounds the famotidine portion completely separating it from the ibuprofen portion

The parties dispute whether the proper construction of "a barrier layer" should be limited to a single barrier layer, and whether "comprising" should be construed as "consisting essentially of."[1] (D.I. 68 at 63). The parties do not dispute that "the second portion" should be construed as "the famotidine portion" and "the first portion" should be construed as "the ibuprofen portion." (Tr. at 85).

Alkem argues that through prosecution disclaimer, Horizon narrowed its claim scope to a composition with the specific Opadry® White (YS-1-7003) (hydroxyl propyl methyl cellulose 2910, polyoxyethylene glycol 400, polysorbate 80 and titanium dioxide) barrier layer that surrounds the famotidine, disavowing all others. (D.I. 100 at 1). Alkem contends that throughout the prosecution of the '451 patent, the Applicants focused the claim to a specific barrier layer, Opadry® White (YS-1-7003), in order to advance prosecution. (*Id.* at 2). Alkem maintains that by limiting the claims to a specific barrier layer of Opadry® White (YS-1-7003), the Applicants were able to distinguish prior art in order to secure immediate allowance. (*Id.* at 7–8). To this end, Alkem argues that Horizon clearly and unmistakably relied on the specific barrier layer formulation, disclaiming unclaimed barrier layers and ingredients by relying on the unexpected and surprising results produced specifically by Opadry® White YS-1-7003. (D.I. 68 at 67). Alkem contends that this amounts to more than merely focusing on a preferred embodiment. (D.I. 100 at 7).

[1] While the dispute is styled as involving the construction of "comprised," it is really a dispute about disclaimer and the extent of disclaimer. Defendant's position is that the disclaimer is so great that the practical effect is to turn a "comprising" claim into a "consisting essentially of" claim.

Horizon argues Alkem cannot meet its "high" and "demanding" burden of establishing that the Applicants' statements in the '451 patent specification or its file history evidence disavowal of claim scope, which requires "the alleged disavowing actions or statements made during prosecution be both clear and unmistakable" and cannot be "amenable to multiple reasonable interpretations." (D.I. 94 at 1 (quoting *Avid Tech., Inc. v. Harmonic, Inc.*, 812 F.3d 1040, 1045 (Fed. Cir. 2016) (quoting *Omega Eng'g Inc. v. Raytek Corp.*, 334 F.3d 1314, 1325–26 (Fed. Cir. 2003); *Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d 1352, 1359 (Fed. Cir. 2003))). Horizon argues that the '451 patent specification broadly describes the variety of materials that may compose the barrier layer, as well as formulations in which there are multiple barrier layers. (D.I. 94 at 3). Horizon maintains that the Applicants' "voluntar[y] introduc[tion]" of Opadry® White YS-1-7003 was only to focus on a preferred embodiment. (*Id.* at 3–4). Horizon contends that Alkem's position that Horizon overcame prior art references via prosecution disclaimer is wrong and Alkem has taken the Applicants' statement made during prosecution out of context. (*See generally* D.I. 94). Horizon maintains that when taken in proper context, the Applicants' prosecution statements distinguish the prior art based on the famotidine and ibuprofen limitation and the lack of an enteric barrier layer. (*Id.* at 5–12).

Horizon argues that to the extent the Court finds prosecution disclaimer, the scope of the disclaimer must be limited to the specific combination of ingredients presented by the prior art, and not as to individual ingredients. (*Id.* at 13–15). Alkem responds that the Applicants put the public on notice of the narrowed claim scope and therefore Horizon should not be allowed to limit the scope of the disclaimer to only "the specific combination of elements presented by the prior art." (D.I. 100 at 9). *See Hockerson-Halberstadt, Inc. v. Avia Grp. Int'l, Inc.*, 222 F.3d 951, 957 (Fed. Cir. 2000) ("The prosecution history constitutes a public record of the patentee's

representations concerning the scope and meaning of the claims, and competitors are entitled to rely on those representations when ascertaining the degree of lawful conduct. . . .") (citations omitted).

Regarding the construction of "comprising," the Court finds Alkem's arguments persuasive. The Court agrees with Alkem that the Applicants disavowed other ingredients beyond those listed in the claim term when the Applicants unambiguously narrowed the claim to the Opadry® White YS-1-7003 in multiple exchanges with the Examiner. (D.I. 100 at 7). The Applicants' statements in the prosecution history rise to the level of clear and unmistakable disavowal when, throughout the prosecution, the Applicants demonstrated a clear understanding of a barrier layer consisting specifically of Opadry® White YS-1-7003. (D.I. 75-3, Ex. 15, '451 patent PH, 12/3/2010 Suppl. Resp. at HZNDXS0000335 (stating "the claims have been amended to … focus on an embodiment of the invention that uses Opadry® White (YS-1-7003) as a barrier layer); *id.* at HZNDXS0000338 ("[a]n Opadry® White (YS-1-7003) barrier layer encasing the famotidine portion completely separating it from the ibuprofen portion"); *id.* 11/15/2010 presentation at HZNDXS0000349 ("wherein the barrier layer is Opadry"); *id.*, Ex. 18, '451 patent PH, 4/18/2011 Resp. at HZNDXS0000463 (amending claim to "a barrier layer of Opadry® White (YS-1-7003)"); *id.* at HZNDXS0000471 ("[t]he current claims specify that the barrier layer is Opadry White (YS-1-7003)"); *id.* (distinguishing prior art based on current claims with "the limitation that the barrier layer be Opadry White (YS-1-7003)").

Applicants' understanding that the barrier layer of the invention consisted specifically of Opadry® White YS-1-7003 is further evidenced by the history of the claims themselves. Since the first claim amendments, and continuing throughout a majority of the prosecution, the initial eleven claims were method claims (which were eventually cancelled) and the relevant claim

language in claim 12 (which eventually issued as claim 1) recited "an Opadry® White (YS-1-7003) barrier layer" or "a barrier layer of Opadry® White YS-1-7003." *Id.* at HZNDXS0000463; Ex. 15, '451 patent PH, 12/3/2010 Suppl. Resp. at HZNDXS0000332. As Horizon admits, Horizon's claims did not include the at-issue "comprising" language and Opadry® White (YS-1-7003) ingredients until, at the Examiner's suggestion, method claims were combined with the specific composition claims. (D.I. 94 at 12; D.I. 75–3 Ex. 19 ('451 patent PH, 5/6/2011 Interview Summary) at HZNDXS0000523 (suggesting "to combine the method claims with the specific composition comprising OP[A]DRY-White (YS[-]1-7003) for a favorable consideration.") The Court is not influenced by the Examiner's use of "comprising" language as the Interview Summary indicates that the Examiner focused on combining the at-issue claims with other method claims and on the composition of the Opadry® White (YS-1-7003), rather than the "comprising" language itself. *Id.* More significantly, the Applicants' disclaiming statements carry more import than the Examiner's remarks. *See Springs Window Fashions LP v. Novo Indus., L.P.*, 323 F.3d 989, 995 (Fed. Cir. 2003) (stating "the examiner's remarks do not negate the effect of the applicant's disclaimer.") Thus, while the claims were amended in response to the Examiner's suggestion, so that they included the "comprising" language and the Opadry® White (YS-1-7003) ingredients, the amendments resulted in no increase in scope regarding the barrier layer. (D.I. 75–4, Ex. 20, 8/11/2011 Suppl. Amendment at HZNDXS0000562–65; *id.*, Ex. 21, HZNDXS0000572–78).

Applicants repeatedly and unambiguously disclaimed ingredients beyond Opadry® White (YS-1-7003) by overcoming prior art references because of the unexpected and surprising results of the Opadry® White (YS-1-7003) barrier layer. (D.I. 75-3 at HZNDXS0000470 (prior art "Sims does not teach a barrier layer of Opadry White (YS-1-7003) completely surrounding the

famotidine separating famotidine from the ibuprofen portion."); *id.* ("[n]one of those references, either alone or in combination, describes the use of Opadry White (YS-1-7003) to surround the famotidine portion completely separating it from the ibuprofen portion."); *id.* at HZNDXS0000471–72 (distinguishing Opadry Aqueous Moisture Barrier (AMB), Sepifilm LP, and Eudragit barrier layers of prior art Ibanez because those barrier layers contain ingredients not found in Opadry® White (YS-1-7003)); *id.* at HZNDXS0000472–73 (distinguishing prior art Proehl because it used Opadry® White (YS-1-7003) with only one additional ingredient, 5% PEG 3350, and was not "a barrier layer that is simply Opadry (YS-1-7003)."). The Applicants further distinguished Proehl because "Proehl would not have provided the artisan of ordinary skill at the time the invention was made any basis for selecting the barrier layer recited in the instant claims," which at the time, was Opadry® White (YS-1-7003). *Id.* at HZNDXS0000473.

Regarding the construction of "a barrier layer," the Court is not persuaded Alkem has reached its "high" and "demanding" burden to demonstrate that the Applicants' statements made during prosecution rise to the "clear and unmistakable" level required by prosecution disclaimer. *Avid Tech.*, 812 F.3d at 1045 (quoting *Omega Eng'g Inc.*, 334 F.3d at 1325–26 (Fed. Cir. 2003)). Unlike the clear and unmistakable disavowal of barrier layer ingredients beyond Opadry® White (YS-1-7003), Alkem does not point to statements in the prosecution history to demonstrate that the Applicants disclaimed that the specific ingredients contained in Opadry® White (YS-1-7003) could not be in more than one barrier layer. (*See generally* D.I. 100). The most that Alkem points to for disclaimer of more than one barrier layer is a schematic illustration of the composition with the Opadry® White (YS-1-7003) barrier layer encased famotidine (D.I. 68 at 69), but this does not amount to "clear and unmistakable" prosecution disclaimer.

Regarding the scope of the disclaimer, the Court agrees with Alkem that the Applicants put the public on notice that they were narrowing the scope of their claims to specify that the barrier layer is Opadry® White (YS-1-7003), and the disclaimer should not be limited to the specific combination of elements presented by the prior art. (D.I. 100 at 9; *see Fenner Invs., Ltd. v. Cellco P'ship*, 778 F.3d 1320, 1323 (Fed. Cir. 2015) ("Any explanation, elaboration, or qualification presented by the inventor during patent examination is relevant, for the role of claim construction is to 'capture the scope of the actual invention' that is disclosed, described, and patented." (citation omitted)).

V. CONCLUSION

The Court construes the disputed term as set forth above.